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FORM PTO-1449 (Modified)
\ LIST OF PATENTS AND PUBLICATIONS
FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT
(Use several sheets if necessary)
Sheet 1 of 4

In the Application of CHIEN ET AL.

Serial No.: DIV of 09/881,239

Art Unit: Unassigned

Filed: On even date

Examiner: Unassigned

Title: HCV ANTIGEN: ANTIBODY COMBINATION ASSAY

U.S. PATENT DOCUMENTS

Exam.l nit.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
ZL	A1	5,350,671	September 27, 1994	Houghton et al.		ļ 	<u> </u>
ZL	A2	5,712,087	January 27, 1998	Houghton et al.			ļ
ZL	А3	5,843,752	December 1, 1998	Dasmahapatra et al.			
ZL	Α4	5,871,904	February 16, 1999	Kashiwkuma et al.	· ·	ļ	<u> </u>
ZL	A5	5,990,276	November 23, 1999	Zhang et al.			
ZL	A6	6,171,782	January 9, 2001	Houghton et al.		·	<u> </u>

FOREIGN PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Trans YES	lation NO
ZL	B1	WO 93/00365	January 7, 1993	PCT		<u> </u>	ļ	
ZL	B2	WO 94/01778	January 20, 1994	PCT			<u> </u>	
ZL	В3	WO 97/44469	November 27, 1993	PCT				
ZL	B4	0 318 216 B2	May 31, 1989	EPO		<u> </u>		

Examiner:

/Zachariah Lucas/

Date Considered:

06/01/2006

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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet 2 of 4

In the Application of CHIEN ET AL.

Serial No.: DIV of 09/881,239

Art Unit: Unassigned

Filed: On even date

Examiner: Unassigned

Title: HCV ANTIGEN: ANTIBODY COMBINATION ASSAY

ZL	B5	0 388 231	September 19, 1990	EPO		
ZL	В6	0 450 931	October 9, 1991	EPO		
ZL	B7	0 472 207 A2	February, 1992	EPO		

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Exam. Init.	Ref. Desig.	Description
ZL	C1 ^r	Beld et al., "Evaluation of Automated RNA-Extraction Technology and a Qualitative HCV Assay for Sensitivity and Detection of HCV RNA in Pool-Screening Systems," Transfusion 40:575-579 (2000)
ZL	C2	Chen et al., "Human and murine antibody recognition is focused on the ATPase/helicase domain, but not the protease domain to the hepatitis C virus non-structural 3 protein," Hepatology 28:219-224, 1998
ZL	СЗ	Chien et al., "Diagnosis of Hepatitis C virus (HCV) Infection Using an Immunodominant Chimeric Polyprotein to Capture Circulating Antibodies: Revaluation of the Role of HCV in Liver Disease," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 89:10011-10015 (1992)
ZL	C4	Chien et al., "Use of Recombiant HCV Antigen in the Serodiagnosis of Hepatits C virus Infection: significant Improvement in HCV Antibody Detection as Compared With eht First Generation HCV C100-3 ELISA and the Synthetic Peptide EIA Tests," Journal of Gastroenterology and Hepatology 8:S33-39 (1993)
ZL	C5	Chien et al., "Distinct Subtypes of Hepatitis C Virus Defined by Antibodies Directed to the Putative Core, NS4, and NS5 Region Polypeptides," Virol. Hepatitis and Liver Disease 320-324 (1994)

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Date Considered:

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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet 3 of 4

In the Application of CHIEN ET AL.

Serial No.: DIV of 09/881,239

Art Unit: Unassigned

Filed: On even date

Examiner: Unassigned

Title: HCV ANTIGEN: ANTIBODY COMBINATION ASSAY

Exam. Init.	Ref. Desig.	Description
ZL	C6	Choo et al., "Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome," Science 244:359-362 (1989)
ZL	C7	Choo et al., "Hepatitis C Virus: The Major Causative Agent of Viral Non-A, Non-B Hepatitis," <i>British Medical Bulletin</i> 46:423-441 (1990)
ZL	C8	Cruse et al., Illustrated Dictionary of Immunology, CRC Press, Boca Raton FL, 1995, page 76
ZL	C9	Ebeling et al., "Recombinant Immunoblot Assay for Hepatitis C Virus Antibody as Predictor of Infectivity," <i>Lancet</i> 335:982-983 (1990)
ZL	C10	Houghton et al., "Molecular Biology of the Hepatitis C Viruses: Implications for Diagnosis, Development and Control of Viral Diesease," Hepatology 14:381-388 (1991)
ZL	C11	Kotwal et al., "Detection of Acute Hepatitis C Virus Infection by ELISA Using a Synthetic Peptide Comprising a Structural Epitope," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 89:4486-4489 (1992)
ZL	C12	Kuo et al., "An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non B Hepatitis," <i>Science</i> 244:362-364 (1989)
ZL	C13	Pereboeva et al., "Hepatitis C epitopes from phage-displayed cDNA libraries and improved diagnosis with a chimeric antigen," J. Medical Virology 60:144-151, 2000
ZL	C14	van der Poel et al., "Infectivity oif Blood Seropositive for Hepatitis C Virus Antibodies," Lencet 335:558-560 (1990)

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Date Considered:

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Atty Dkt No. 2302-16073.10

PP16073.021

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FORM PTO-1449 (Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary) Sheet 4 of 4

In the Application of CHIEN ET AL.

Serial No.: DIV of 09/881,239

Art Unit: Unassigned

Filed: On even date

Examiner: Unassigned

Title: HCV ANTIGEN: ANTIBODY COMBINATION ASSAY

Exam. Init.	Ref. Desig.	Description
ZL	C15	van der Poel et al., "Confirmation of Hepatitis C Virus Infection by New Four-Antigen Recombinant Immunoblot Assay," <i>Lancet</i> 337:317-319 (1991)
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Date Considered:

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

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Sheet	1		of	2	

Complete if Known							
Application Number	10/643,853						
Filing Date	August 19, 2003						
First Named Inventor	Chien et al.						
Group Art Unit	1632						
Examiner Name	Not Assigned						
Attorney Docket Number	PP16073.021 (2300-16073.10)						

U.S. PATENT DOCUMENTS						
		U.S. Patent Document			Date of Publication of Cited	
Examiner Initials*	Cite No.1	Number	Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Document MM-DD-YYYY	
ZL	AA	5,683,864		Choo Qui-Lim et al.	11-04-1997	
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	No.	Office ³	Number ⁴	Kind Code ⁵ (if known)	Name of Patentee or Applicant of Cited Document	of Cited Document MM-DD-YYYY	T ⁶	
ZL	BA	PCT	WO 94/25601		Innogenetics NV; Maertens Geert (BE) and Stuyver Lieven (BE)	11-10-1994		
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Examiner		Date	
Signature	/Zachariah Lucas/	Considered	06/01/2006
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Unique citation designation number.

See attached Kinds of U.S. Patent Documents.

³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08A (08-00)

Substitute for form 1449A/PTO			0	Complete if Known		
ı				Application Number	10/643,853	
IN	FORMATION	ON DI	SCLOSURE	Filing Date	August 19, 2003	
S	FATEMENT	BY A	APPLICANT	First Named Inventor	Chien et al.	
			•	Group Art Unit	1632	
	(use as many s	sheets a	s necessary)	Examiner Name	Not Assigned	
Sheet	2	of	2	Attorney Docket Number	PP16073.021 (2300-16073.10)	

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T		
ZL	CA	CHIEN et al., "Use of a Novel Hepatitis C Virus (HCV) Major-Epitope Chimeric Polypeptide for Diagnosis of HCV Infection," Journal of Clinical Microbiology, Washington, DC, US, 37(5):1393-1397 (1999)			
ZL	СВ	KASHIWAKUMA et al., "Detection of Hepatitis C Virus Specific Core Protein in Serum of Patients by a Sensitive Fluorescence Enzyme Immunoassay (FEIA)," Journal of Immunological Methods, Elsevier Science Publishers B.V., Amsterdam, NL, 190(1):79-89 (1996)			
ZL	CC	NING YANG et al., "Examination of IGM Antibody to Hepatitis C and Analysis on Hepatitis C Patients' Sera," Zhonghua Weishengwuxue He Mianyixue Zazhi, 15(4):254-257 (1995) XP001121826			
ZL	CD	QI ZIBAI et al., "Evaluation of the Capabilities for Detecting Anti-HCV Core and NS3 Antibodies with Two Anti-HGV EIA Kits of the Third Generation," Zhonghua Weishengwuxue He Mianyixue Zazhi, 19(5):433-435 (1999) XP001121825			
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	Signature	/Zachariah Lucas/	Considered	06/01/2006

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Unique citation designation number.
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PTO/SB/08A (08-03)

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE work Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO Complete If Known **Application Number** 10/643,853 **INFORMATION DISCLOSURE** Filing Date August 19, 2003 STATEMENT BY APPLICANT First Named Inventor DAVID Y. CHIEN et al. Art Unit 1632 (use as many sheets as necessary) **Examiner Name** Unassigned Sheet of **Attorney Docket Number** PP16073.021 (230-16073.10)

	U.S. PATENT DOCUMENTS+						
Document Number		Document Number					
Examiner Initials*	Cite No. ¹	Number Kind Code ² (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
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FOREIGN PATENT DOCUMENTS								
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Examiner Initials*		Country Code ³	Number ⁴	Kind Code ^a (# Imown)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear	⊤ ⁰
ZL	ВА	EP	0 388 232	A1	09/19/1990	Chiron Corp.		
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Examiner Signature	/Zachariah Lucas/	Date Considered	06/01/2006
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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.